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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,742	12/29/2003	Mark Tawa	TPI-2900C3XC2	2066
23557	7590	09/15/2006	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			ISSAC, ROY P	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/747,742

Applicant(s)

TAWA ET AL.

Examiner

Roy P. Issac

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-6 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

This application claims benefit of 60/486,713 07/11/2003 and claims benefit of 60/459,501 04/01/2003 and claims benefit of 60/456,608 03/21/2003 and claims benefit of 60/456,027 03/18/2003 and claims benefit of 60/441,335 01/21/2003 and claims benefit of 60/437,516 12/30/2002 and is a continuation in part of 10/601,092 06/20/2003 abandoned which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 and is a CIP of PCT/US03/19574 06/20/2003 which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 and said 10/601,092 06/20/2003 claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/428,515 11/22/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003

This application 10/747,742 is a CIP of PCT/US03/19574 06/20/2003 which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 This application 10/747,742 is a CIP of PCT/US03/41273 12/24/2003 which is a CIP of 10/601,092 06/20/2003 ABN which claims benefit of 60/390,881

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06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 and said PCT/US03/41273 12/24/2003 is a CIP of 10/660,202 09/11/2003 which is a CIP of PCT/US03/27772 09/04/2003 which is a CIP of 10/378,956 03/03/2003 which claims benefit of 60/360,768 03/01/2002 and said PCT/US03/27772 09/04/2003 claims benefit of 60/451,213 02/28/2003 and claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/487,064 07/11/2003 and said 10/660,202 09/11/2003 is a CIP of 10/637,829 08/08/2003 which is a DIV of 10/295,995 11/18/2002 PAT 6,699,840 and said 10/295,995 is a CON of 10/232,589 09/03/2002 PAT 6,559,293 which claims benefit of 60/406,974 08/30/2002 and claims benefit of 60/380,288 05/15/2002 and claims benefit of 60/356,764 02/15/2002 and said 10/660,202 is a CIP of 10/449,307 05/30/2003 PAT 7,078,526 which claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/444,315 01/31/2003 and claims benefit of 60/439,282 01/10/2003 and claims benefit of 60/384,152 05/31/2002 and said 10/660,202 is a CIP of 10/601,092 06/20/2003 ABN and claims benefit of 60/451,213 02/28/2003 and claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/487,064 07/11/2003.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, drawn to a pharmaceutical composition comprising a propylene glycol solvate of an active pharmaceutical ingredient, classified in class 424, subclass 400.
- II. Claims 3-4, drawn to a method of preparing polyethylene glycol solvate of an active pharmaceutical ingredient, classified in class 424, subclass 400.
- III. Claims 5-6, drawn to a method of decreasing hygroscopicity, classified in class 424, subclass 400.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product can be made by a materially different process. For example, polypropylene can be used as a surfactant in combination with an active pharmaceutical ingredient to produce a solvate. (U.S. Patent No. 6,054,136; Claim 14, Column 10, lines 10-50; PTO-892, Cited by the examiner)

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product can be practiced with another materially different product. For example, the hygroscopicity can be decreased by the use of high molecular weight polyethylene glycol. (U.S. Patent No. 4925674; Column 6, lines 17-25: PTO-892, Cited by the examiner).

37 CFR 1.141(b), quoted below, provides that it is proper to restrict between the three inventions when the process of making is distinct from the product. (MPEP 806.05(i)). As discussed above the product is distinct from the process of making, and as such the restriction is proper.

(b) Where claims to all three categories, product, process of making, and process of use, are included in a national application, a three way requirement for restriction can only be made where the process of making is distinct from the product. If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product even though a showing of distinctness between the product and process of using the product can be made.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

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be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because the above set forth restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See MPEP § 812.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

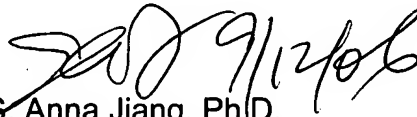
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Roy P. Issac
Patent Examiner
Art Unit 1623


S. Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623